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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,284	04/25/2000	Uwe Sonnewald	VOS-12 CON	8936

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/558,284

Applicant(s)

SONNEWALD ET AL.

Examiner

Cynthia Collins

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-13 and 15-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The Amendment filed August 29, 2002, paper no. 17, has been entered.

Claims 1, 2-5 and 8-20 are newly amended.

Claims 21-32 are newly added.

Claims 1-32 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Newly amended claim 14 is directed to an invention nonelected with traverse in Paper No. 14, namely Group II, drawn to a vector comprising a DNA sequence encoding a protein with the biological activity of a 2-deoxyglucose-6-phosphate phosphatase and at least one further recombinant DNA molecule. Accordingly, claim 14 is withdrawn from consideration as being directed to a nonelected invention.

This application currently contains claims 6, 7 and 14 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

Applicant's IDS form 1449, filed August 29, 2002, Paper No. 19, was not available to the Examiner at the time of the instant office action. Applicant is requested to submit a copy of the submitted form 1449 for the Examiner's consideration.

Claim Rejections - 35 USC § 112 and § 101

Claims 1-5, 8-9, 13 and 15-18 remain rejected, and newly added claims 21 and 24-32 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed March 25, 2002.

Applicant's arguments filed August 29, 2002, have been fully considered but they are not persuasive.

Applicant points out that at the time of the priority date several 2-deoxyglucose-6-phosphate phosphatases were known in the art, including two genes from yeast and a gene from *E. coli*. Applicant argues that the specification makes clear that the invention is not limited to the exemplified 2-DOG-6-P phosphatase. Applicant points out that the claims as amended are now directed to sequences that hybridize under stringent conditions, and an amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:2. Applicant argues that the DNA sequences recited in the amended claims are structurally similar and that a representative number of species is disclosed (reply pages 11-12).

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The Office maintains that Applicant has described only one species of the claimed genus, the nucleotide sequence of SEQ ID NO:1 encoding the amino acid sequence of SEQ ID NO:2. Applicant has not described or characterized any sequence that hybridizes to SEQ ID NO:1 that has 2-deoxyglucose-6-phosphate phosphatase activity. Applicant has not described or characterized any polypeptide sequence that has an amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:2 and that has 2-deoxyglucose-6-phosphate phosphatase activity. Furthermore, structurally similar sequences are not adequately described in the absence of evidence of their functional similarity. Additionally, the Office notes that claim 1 does not recite any structure for the DNA sequence encoding a 2-deoxyglucose-6-phosphate phosphatase.

Claims 1-5, 8-13 and 15-20 remain rejected, and newly added claims 21-32 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant DNA molecule comprising a DNA sequence of SEQ ID NO:1 encoding 2-deoxyglucose-6-phosphate phosphatase of SEQ ID NO:2 operably linked to plant regulatory sequences, for a vector, a host cell, a kit, transgenic plants, plant cells, tissue, harvest products and propagation material comprising said recombinant DNA molecule, and for a process for selecting transformed plant cells comprising transforming plants cells with said recombinant DNA molecule and selecting transformed cells on 2-deoxyglucose containing media, use of said recombinant DNA molecule to produce transgenic plant plants, cells and or tissue, and use of said recombinant DNA molecule as a selectable marker in plant cell and tissue culture, does not reasonably provide enablement for other recombinant DNA molecules comprising other DNA sequences, or for products comprising said other recombinant DNA molecules, or for processes

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using said other recombinant DNA molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed March 25, 2002.

Applicant's arguments filed August 29, 2002, have been fully considered but they are not persuasive.

Applicant argues that the specification does teach how to make and use the sequences recited in claims 1 and 2 as amended, and points in particular to pages 4, 5, 6, 19 and 24. Applicant also points to the cited reference of Randez-Gil et al. which describes the identification of a 2-deoxyglucose-6-phosphate phosphatase gene. Applicant asserts that it would not have required undue experimentation for one skilled in the art to determine sequences that encode a 2-deoxyglucose-6-phosphate phosphatase gene at the time of filing (reply pages 14-15). Applicant further argues that the specification teaches that the expression of 2-deoxyglucose-6-phosphate phosphatase results in a decrease of 2-deoxyglucose-6-phosphate in plants, and that accordingly one skilled in the art would be able to routinely determine sequences that encode a 2-deoxyglucose-6-phosphate phosphatase (reply page 15).

The Office maintains that the specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, which nucleic acid sequences that hybridize to SEQ ID NO:1 or which amino acid sequences at least 90% identical to SEQ ID NO:2 would encode a 2-deoxyglucose-6-phosphate phosphatase that could be used to practice the claimed invention, as the specification discloses only one sequence encoding a 2-deoxyglucose-6-phosphate phosphatase, the nucleic acid sequence of SEQ ID NO:1. The Office

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maintains that the ability of one skilled in the art to isolate or express in plants a 2-deoxyglucose-6-phosphate phosphatase gene does not enable the claimed invention, as the undue experimentation lies in the process of discriminating between operative and inoperative sequences before they are tested for function. The claimed invention is not enabled in the absence of guidance with respect to what structure hybridizing sequences encoding a 2-deoxyglucose-6-phosphate phosphatase activity would have, or what structure polypeptide sequences at least 90% identical to SEQ ID NO:2 and exhibiting 2-deoxyglucose-6-phosphate phosphatase activity would have. If the coding sequence has 2-deoxyglucose-6-phosphate phosphatase activity, the complementary sequence would not encode a 2-deoxyglucose-6-phosphate phosphatase protein.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of hybridizes "under stringent conditions". It is unclear under what stringency conditions would yield the DNA sequences, as those skilled in the art define stringent conditions differently. It is suggested that the claim be amended to recite specific hybridization conditions.

Claim 19 incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claimed method does not result in the production of a transgenic plant, plant cell tissue or combination thereof as set forth in the preamble.

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Claim Rejections - 35 USC § 103

Claims 1-5, 8-13 and 15-20 remain rejected, and newly added claims 21-32 are rejected, under 35 U.S.C. 103(a) as being unpatentable over Randez-Gil et al. (1995, Yeast, Vol. 11, pages 1233-1240, Applicant's IDS) in view of Herrera-Estrella et al. (1983, The EMBO Journal, Vol. 2, pages 987-995, Applicant's IDS), and in further view of Zemek et al. I (1975, Z. Pflanzenphysiol. Bd., Vol. 76, pages 114-119, Applicant's IDS) and Zemek et al. II (1976, Z. Pflanzenphysiol. Bd., Vol. 77, pages 95-98, Applicant's IDS). for the reasons of record set forth in the office action mailed March 25, 2002.

Applicant's arguments filed August 29, 2002, have been fully considered but they are not persuasive.

Applicant argues that one skilled in the art would not have been motivated to combine the cited references with a reasonable degree of success, as none of Herrera-Estrella et al. or Zemek I and II mention the 2-deoxyglucose-6-phosphate phosphatase gene. Furthermore, Applicant argues that Randez-Gil et al. teach away from the claimed invention because Randez-Gil et al. recite that the actual function of 2-deoxyglucose-6-phosphate phosphatase in regular yeast metabolism is not known, indicating that further investigation of 2-deoxyglucose-6-phosphate phosphatase is required, and one skilled in the art would not have thought to combine the cited references in an organism foreign to yeast (reply page 23). Applicant further argues that none of Zemek I and II or Randez Gil et al. teach a recombinant DNA sequence comprising a polynucleotide encoding 2-deoxyglucose-6-phosphate phosphatase operably linked to a plant promoter, or processes or products involving plant transformation and selection of transformants. Furthermore, the cited reference of Herrera-Estrella et al. only refers to processes and products

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involving genes other than 2-deoxyglucose-6-phosphate phosphatase, and does not suggest the use of 2-deoxyglucose-6-phosphate phosphatase in their place. Applicant argues that Herrera-Estrella et al. teach away from the claimed invention, as the methods described were not always effective and frequently negatively affected plant regeneration (reply pages 23-24).

The Office maintains that the success of Randez-Gil et al. in using a DNA sequence of SEQ ID NO:1 encoding 2-deoxyglucose-6-phosphate phosphatase of SEQ ID NO:2 as a selectable marker in yeast cell culture, and the success of Herrera-Estrella et al. in using recombinant DNA molecules encoding other microbial enzymes as selectable markers in plant cell culture, would motivate one skilled in the art to use a DNA sequence of SEQ ID NO:1 encoding 2-deoxyglucose-6-phosphate phosphatase of SEQ ID NO:2 as a selectable marker in plant cell culture, especially given the teachings of Zemek et al. that 2-deoxyglucose inhibits the growth plant cell cultures. That the actual function of 2-deoxyglucose-6-phosphate phosphatase in regular yeast metabolism is not known is not germane to the instant invention, as the claimed invention is not directed to any aspect of yeast metabolism. The claimed invention only requires a 2-deoxyglucose-6-phosphate phosphatase activity. That the methods described by Herrera-Estrella et al. were not always effective and frequently negatively affected plant regeneration is also not germane, as Herrera-Estrella et al. were ultimately successful, and the optimization of selection conditions necessarily requires the use of a wide range of selection conditions, many of which are suboptimal.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

November 18, 2002


PHUONG T. BUI
PRIMARY EXAMINEE 11/18/02